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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,228	07/18/2003	Timothy J. Hagen	01160/1	2720

7590

11/18/2005

Pharmacia Corporation  
Global Patent Department  
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EXAMINER

STOCKTON, LAURA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/623,228

**Applicant(s)**

HAGEN ET AL.

**Examiner**

Laura L. Stockton, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on May 5, 2005 and August 25, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-10,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/5/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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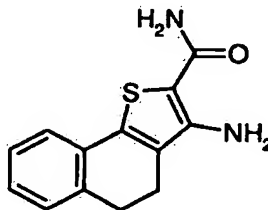
## DETAILED ACTION

Claims 1, 4-6 and 8-22 are pending in the application.

### *Election/Restrictions*

Applicants' election with traverse of Group I, and the species of Example 1 on page 21 (reproduced below), in the reply filed on November 4, 2004 was acknowledged in the previous Office Action.

#### Examples 1



3-amino-4,5-dihydronaphtho[1,2-b]thiophene-2-carboxamide

**Note:** The elected species of Example 1 is not embraced by the currently amended claims.

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The scope of the elected invention that has been examined, inclusive of the species of Example 1, is as follows:

**A** is an unsubstituted  $(CH_2)_m$ ;

**R<sup>1</sup> and R<sup>2</sup>** are independently selected from the group consisting of: cyano, nitro, hydroxyl, alkyl, hydroxyalkyl, haloalkyl, alkoxy, haloalkoxy, amidine, guanidine,  $CONHR^5$ ,  $NHR^5$  and  $NHCXNHR^5$ ; and

all other variables are as defined.

The requirement was deemed proper and made FINAL in the previous Office Action.

Subject matter not embraced by the above identified scope of the elected invention and claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

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Applicant timely traversed the restriction (election) requirement in the reply filed on November 4, 2004.

***Information Disclosure Statement***

The Information Disclosure Statement filed on May 5, 2005 has been considered by the Examiner.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

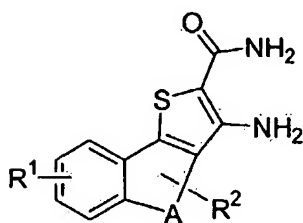
***Priority***

Applicants' Provisional Application 60/397,052 filed July 19, 2002 has been reviewed because of intervening art. The entire genus of the instant claimed compounds of formula I in independent claim 1

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could not be found in the provisional application. See following the class of compounds found in Provisional Application 60/397,052 (reproduced in-part).

A class of compounds, which are useful in treating cancer, inflammation, and inflammation related disorders, is defined by Formula I:



Wherein:

A is  $(CH_2)_m$  or  $(CH_2)_m-W-(CH_2)_n$ ;

W is  $S(O)_p$ , O,  $CH=N$ ,  $N(O)=CH$ , and  $NR^4$ ;

m is 0 to 3, inclusive;

n is 0 to 3, inclusive;

p is 0 to 2, inclusive;

$R^1$  is selected from the group consisting of: sulfamyl, halo, alkyl, alkoxy, hydroxyl and haloalkyl,  $CF_3$ ,  $COCF_3$ , CN,  $NO_2$ , hydrido,  $OR^3$ ,  $OCOOR^3$ ,  $CO_2H$ ,  $CO_2R^3$ ,  $CONH_2$ ,  $CONHR^3$ ,  $CON(R^3)_2$ ,  $COR^3$ ,  $SR^3$ ,  $SOR^3$ ,  $SCOOR^3$ ,  $SO_2R^3$ ,  $NH_2$ ,  $NHR^3$ ,  $NR^3R^3$ ,  $NR^3COR^3$ ,  $NR^3CONHR^3$ ,  $NR^3SO_2R^3$ ,  $NR^3SO_2NHR^3$ ,  $SO_2NHR^3$ ,  $SO_2N(R^3)_2$ ;

Further, the instant transmittal sheet indicates that the instant claimed application is a CIP of Provisional Application 60/397,052. Therefore, entire genus of the

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instant claimed compounds of formula I as instantly claimed is not afforded the benefit of the filing date of the provisional application. The following rejection still applies.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 8-10, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Callahan et al. {WO 03/086309}.

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Callahan et al. disclose, for instance, Example 8 on page 29, which is embraced by the instant claimed invention.

### ***Response to Arguments***

Applicants' arguments filed May 5, 2005 have been fully considered. Applicants argue that none of the compounds disclosed by Callahan et al., that are embraced by the instant claimed invention, were disclosed in the provisional priority document (60/371,946) of Callahan et al., and thus these compounds are not entitled to the priority date of April 11, 2002. Therefore, Applicants conclude that the compounds of Callahan et al. do not anticipate the instant claimed invention.

In response, the instant claimed invention, currently amended, is still anticipated by Callahan et al. because Applicants cannot rely on the disclosure of their own provisional application 60/397,052 filed



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July 19, 2002 in overcoming the anticipation rejection.

As shown above, Applicants' provisional application

60/397,052 discloses compounds of Formula (I) having a carboxamide group fixed at the 2-position and an amino group fixed at the 3-position of the tricyclo ring. A compound such as Example 8 (reproduced below) in

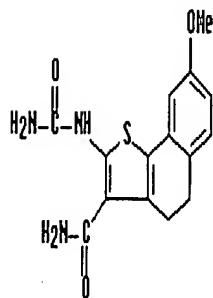
Callahan et al., which has a urea group attached at the 2-position and a carboxamide group attached at the 3-position of the tricyclo ring, is afforded the

International filing date of the WO which is

April 11, 2003.

RN 617688-44-5 CAPLUS

CN Naphtho[1,2-b]thiophene-3-carboxamide, 2-[(aminocarbonyl)amino]-4,5-dihydro-8-methoxy- (9CI) (CA INDEX NAME)



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Applicants' best date for the entire scope of the instant claimed invention is the filing date of the instant application, which is July 18, 2003. For all the reasons given above, Callahan et al. anticipate the instant claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al. {WO 03/086309} and Bastian {U.S. Pat. 4,183,943}, each taken alone or in combination with each other.

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*Determination of the scope and content of the prior art (MPEP*

*§2141.01)*

Applicants claim tricyclic containing thiophene compounds. Callahan et al. (page 7; page 9, lines 6-16; page 12, starting at line 12 thru page 16; and especially Example 8 on page 29) and Bastian (column 1, lines 10-40; column 5, lines 9-17; column 6, lines 22-33; and especially Examples 7 and 12 in column 4) teach tricyclic containing thiophene compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

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***Finding of prima facie obviousness--rational and motivation (MPEP******§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-thrombin). Further, since Callahan et al. (page 9, lines 6-16) and Bastian (column 5, lines 9-17) each teach that the tricyclic containing thiophene compounds are useful in treating, for example, asthma, the combination of the two references would also teach Applicants' claimed invention.

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating inflammatory disorders. The instant claimed invention would have been suggested

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and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

### ***Response to Arguments***

Applicants' arguments filed May 5, 2005 have been fully considered. Applicants argue that neither Callahan et al. nor Bastian, either taken separately or together, described every element of the instant claimed invention. In response, Callahan et al. disclose (as stated above) and teach compounds embraced by the instant claimed invention. See, for instance, Example 8 on page 29 of Callahan et al. Further, Bastian generically describe the present claimed compounds. See in Bastian, for example, the compounds of formula I wherein  $R_1$  is alkoxy;  $R_2$ ,  $R_3$  and  $R_6$  are each hydrogen;  $n$  is zero;  $m$  is 2;  $R_4$  is alkyl; and  $R_5$  is carboxamide. For all the reasons given above, the rejection is deemed proper and is maintained.

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***Allowable Subject Matter***

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed

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until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on November 4, 2004. A complete reply, if any, to the final rejection must include cancellation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

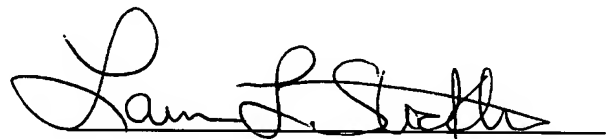
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

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(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

November 15, 2005